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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/886,041	06/22/2001	Tai-He Xia	41491	5481

1609 7590 09/12/2002

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EXAMINER
BRANNOCK, MICHAEL T

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 09/12/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/886,041	Tal-He XIA et al.
Examiner	**Art Unit**
Michael Brannock, Ph.D	1646

-- The MAILING DATE of this communication appears on the cover sh t with the correspondence address --

Period for R ply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Apr 22, 2002*

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-25* is/are pending in the applica

4a) Of the above, claim(s) _____ is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-25* are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-8, 11-17, drawn to polynucleotides, vectors, host cells and methods of producing a polypeptide, classified in class 536, subclass 23.5.

II. Claims 9 and 10, drawn to polypeptides, classified in class 530, subclass 350.

III. Claims 18 and 19, drawn to antibodies, classified in class 530, subclass 388.22.

IV. Claims 20 and 25, drawn to methods of treatment, classification dependent on the chemical nature of the administered compound.

V. Claims 21-23, drawn to methods of identifying agonists and antagonists, classified in class 435, subclass 7.21.

VI. Claim 24, drawn to compositions comprising agonists or antagonists, classification dependent on the chemical nature of the agonists or antagonists.

2. The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to <u>different</u> products, restriction is deemed to be proper because these products appear to constitute patentably distinct inventions for the following reasons: Groups I-III and VI are directed to products that are distinct both physically and functionally, and are not required one for the other, and are therefore patentably distinct. Further, the protein of Group II can be prepared by processes which are materially different from recombinant DNA expression of Group I, such as by chemical synthesis, or by isolation and purification from natural sources. Additionally, the DNA of Group I can be used

other than to make the protein of Group II, such in the gene therapy or as a probe in nucleic acid hybridization assays. The protein of Group II can be used in materially different methods other than to make the antibody of Group III, such as in therapeutic or diagnostic methods (e.g., in screening). Although the antibody of Group III can be used to obtain the DNA of Group I, it can also be used in materially different methods, such as in various diagnostic (e.g., in as a probe in immunoassays or immunochromatography), or therapeutic methods. Although, the protein Group II can be used to identify the agonist or the antagonist of Group VI, the protein could also be used to produce the antibody of Group III. Although, the DNA of Group I can be used to produce the protein of Group II which can be used to identify the agonist or the antagonist of Group VI, the DNA could also be used to as a diagnostic probe. The agonist and the antagonist of Group VI are distinct from the protein and from the DNA because the agonist and antagonist could be obtained from sources other than those employing the protein of Group II or the DNA of Group I, such as from commercial vendors. Furthermore, the antibody of Group III is distinct from the antagonist and the agonist of Group VI, because an antibody which binds to a protein does not necessarily alter the activity of the protein as required of an antagonist or agonist.

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Groups IV and V are directed to methods that are distinct both physically and functionally, and are not required one for the other. Group IV requires a method of

treatment, which is not required by Group V. Group V requires an assay of receptor activity, which is not required by Group IV. Although the method of Group IV requires agonists or antagonists, as recited in the claims of Group V, the compositions required of Group IV could be acquired from sources other than the methods of Group V, e.g. such compositions may be commercially available.

The polynucleotides of Group I are related to the method of Group V as product and process of use, e.g. the polynucleotides could be used to produce the protein used in the assay. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotides of Group I are patentably distinct from the method of Group V because the polynucleotides of Group I can be used in ways that are materially and functionally different than the method, such as a probe for diagnostic purposes.

The polypeptides of Group II are related to the method of Group V as product and process of use, e.g. the polynucleotides could be used to produce the protein used in the assay. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides of Group II are patentably

distinct from the method of Group V because the polypeptides of Group II can be used in ways that are materially and functionally different than the method, such as to produce the antibodies of Group III.

The polynucleotides of Group I and the polypeptide II are distinct from the method of Group IV because one is not required for the other. Similarly the antibodies of Group III are patentably distinct from each of the methods of Groups IV and V because one is not required for the use of the other.

The agonist and antagonist of Group VI and the methods of Group IV and V are related as product and process of use, and are patentably distinct because, as discussed above, each of the methods of Groups IV and V are materially and functionally distinct from each other.

Therefore, because these inventions are distinct for the reasons given above and because a search and examination of all the groups in one patent application would result in an undue burden, since the searches for the groups are not co-extensive, the classification is different, and the subject matter is divergent, restriction for examination purposes as indicated is proper.

3. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any

amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brannock, Ph.D., whose telephone number is (703) 306-5876. The examiner can normally be reached on Mondays through Thursdays from 8:00 a.m. to 5:30 p.m. The examiner can also normally be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MB

September 7, 2002

YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600